

BIO-RESORT

60-month primary endpoint results of an RCT comparing Orsiro™ DES and Synergy vs. Resolute Integrity

Conclusions

- In this 3,514-patient large, randomized, investigator initiated, all-comers trial, Orsiro™ DES demonstrates non-inferiority to Resolute Integrity while performing equally well as Synergy (primary endpoint Target Vessel Failure (TVF) at 12 months: Orsiro™ 4.7 %, Synergy 4.7 %, Resolute Integrity 5.4 %, p non-inferiority <0.0001).
- At 36 months, in this highly complex patient population, Orsiro™ DES shows favorable outcomes with numerically lower event rates in TVF compared to both Synergy and Resolute Integrity.
- At 60 months, Orsiro™ DES, Synergy, and Resolute Integrity show similar 5-year outcomes of safety and efficacy, including all cause mortality.

Study design

All-comers, multi-center, assessor and patient-blinded, randomized, non-inferiority trial

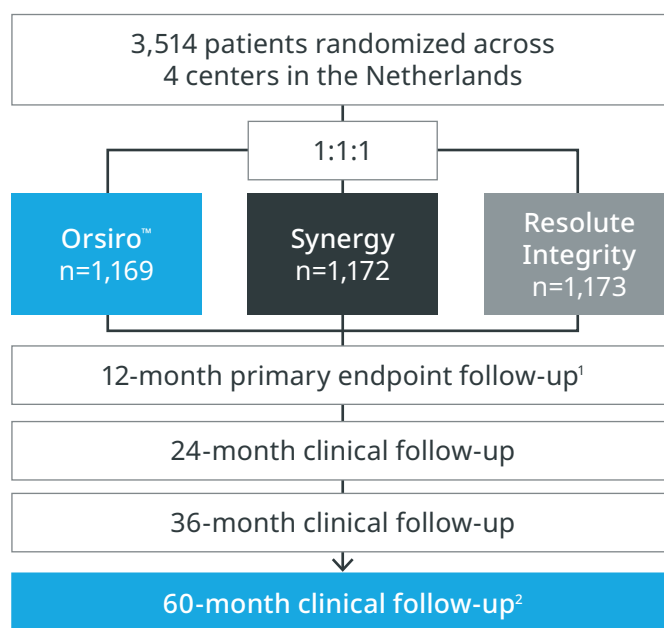
Endpoints

Primary endpoint

- TVF at 12 months defined as the composite of cardiac death, TV-MI or TVR

Secondary endpoints

- Individual components of the primary endpoint
 - All-cause mortality
 - Any MI
 - Target Lesion Failure (TLF) Clinically indicated Target Lesion Revascularization (CI-TLR)
 - Stent Thrombosis (ST)



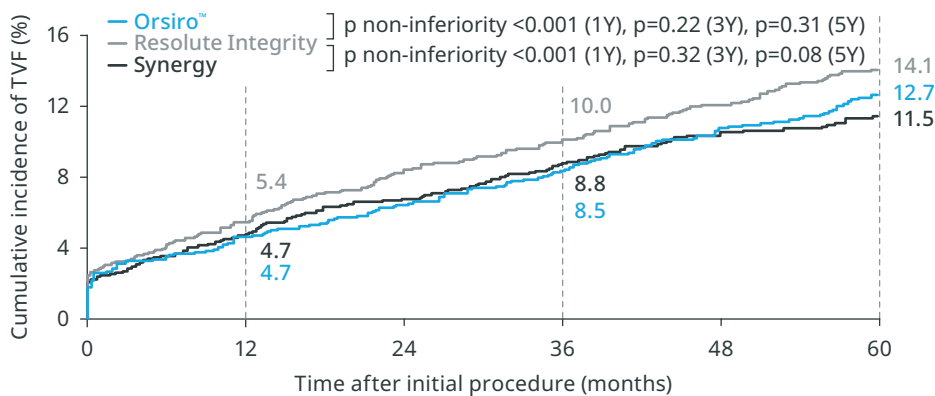
PATIENT CHARACTERISTICS ¹	ORSIRO N=1,169	SYNERGY N=1,172	RESOLUTE INTEGRITY N=1,173
Age, yrs [†]	64.2±10.7	64.0±10.7	63.6±10.9
Male	73 %	72 %	72 %
Smoking	30 %	30 %	31 %
Diabetes mellitus	18 %	17 %	18 %
Previous MI	17 %	16 %	21 %
Previous PCI	18 %	18 %	17 %
Previous CABG	7 %	8 %	8 %
Clinical indication			
ST-Elevation MI (STEMI)	32 %	32 %	28 %
Non-ST-Elevation MI (NSTEMI)	20 %	21 %	23 %
Unstable angina	18 %	16 %	19 %

LESION CHARACTERISTICS ²	ORSIRO N=1,551 [§]	SYNERGY N=1,532 [§]	RESOLUTE INTEGRITY N=1,580 [§]
De novo lesion	96.8 %	97.1 %	96.8 %
Bifurcated lesion	28.6 %	29.1 %	27.7 %
Severe calcification	20.4 %	19.3 %	20.7 %
ACC-AHA lesion class (n)	1,545	1,527	1,573
A/B1	26.3 %	29.0 %	27.8 %
B2/C	73.7 %	71.0 %	72.2 %
Median lesion length (mm)	14.63	14.59	14.74
Minimum lumen diameter (mm)	0.71	0.71	0.70
Reference vessel diameter (mm) [†]	2.75±0.56	2.76±0.56	2.76±0.59
Stenosis (lumen diameter %)	72.8	73.8	72.5

[§] Number of lesions

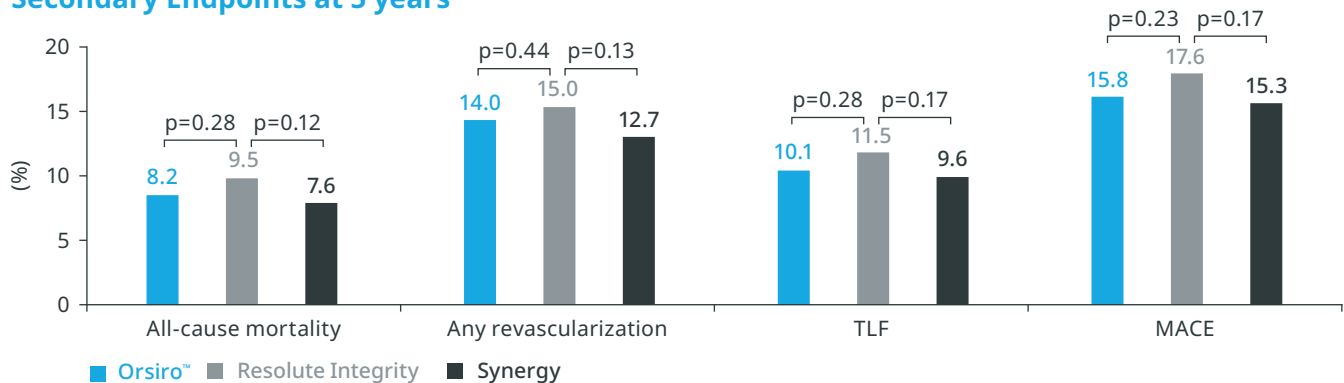
[†] Data shown as mean±SD

Primary endpoint

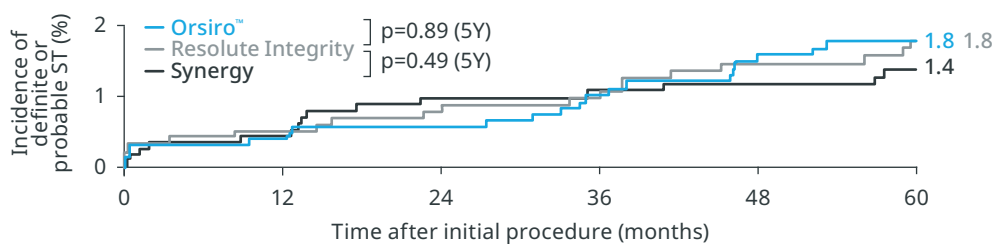


Orsiro™ DES showed similar 5-year safety and efficacy to Synergy and Resolute Integrity.*

Secondary Endpoints at 5 years¹



Definite/Probable Stent Thrombosis^{1,2}



Antithrombotic and Anticoagulant Therapy at 5-year follow-up

	ALL PATIENTS N=2,950		ORSIRO N=994		SYNERGY N=982		RESOLUTE INTEGRITY N=974		P-VALUE
Aspirin	2,288	77.6%	779	78.4%	751	76.5%	758	77.8%	0.58
DAPT	139	4.7%	59	5.9%	37	3.8%	43	4.4%	0.07
With clopidogrel	103	3.5%	39	3.9%	30	3.1%	34	3.5%	0.58
With prasugrel or ticagrelor	36	1.2%	20	2.0%	7	0.7%	9	0.9%	0.02

Principal investigator: Prof. Clemens von Birgelen, Enschede, the Netherlands

References:

- 1 von Birgelen C et al. The Lancet. 2016;388(10060):2607-17.
- 2 Ploumen, Presented: BIO RESORT : 5 Year Outcomes From a Randomized Trial of 3 Drug Eluting Stents in Patients With Coronary Artery Disease.

RCT: Randomized Controlled Trial TVF: Target Vessel Failure TV-MI: Target Vessel Myocardial Infarction TVR: Target Vessel Revascularization MI: Myocardial Infarction, TLF: Target Lesion Failure CI-TLR: Clinically-Indicated-Target Lesion Revascularization ST: Stent Thrombosis.

*Based on 5-year outcomes of the BIO-RESORT trial.

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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BIO-RESORT

12-month High-Bleeding Risk (HBR) subgroup analysis of the BIO-RESORT trial,
RCT Orsiro™ DES and Synergy vs. Resolute Integrity

Conclusions

- Almost 29 % of the BIO-RESORT all-comers had a High-Bleeding Risk (HBR).
- In this subanalysis (n=1,009), the Bioabsorbable Polymer DES (BP-DES) arm, including Orsiro™ DES, showed numerically lower event rates of the primary composite endpoint Target Vessel Failure (TVF) compared to Durable Polymer DES (DP-DES).
- On a product level, Orsiro™ DES alone demonstrated a numerically lower TVF rate (6.0 %) than Synergy (6.9 %), and Resolute Integrity (7.3 %) in HBR patients, respectively. The differences did not reach statistical significance.

Study design

HBR patient stratification of an all-comers, multi-center, assessor and patient-blinded, randomized, non-inferiority trial according to defined established HBR criteria

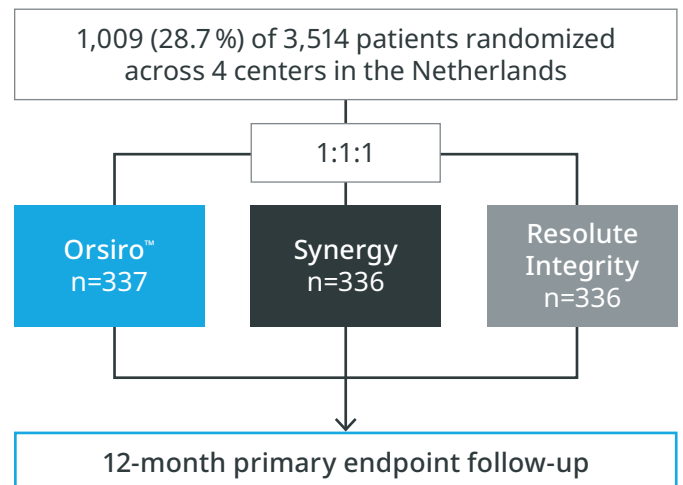
Endpoints

Primary endpoint

- TVF at 12 months defined as the composite of cardiac death, Target Vessel-related Myocardial Infarction (TV-MI), Target Vessel Revascularization (TVR) or Target Lesion Failure (TLF)

Secondary endpoints

- Components of the primary endpoint
- All-cause mortality
- Any MI
- Clinically indicated Target Lesion Revascularization (TLR)
- Stent Thrombosis (ST)

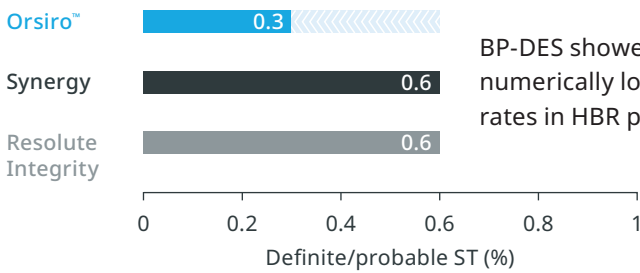


* Synergy is a registered trademark of Boston Scientific

** Resolute and Integrity are registered trademarks of Medtronic Vascular Inc.

12-month clinical endpoints in HBR patients¹

CLINICAL ENDPOINTS	ORSIRO N=337	SYNERGY N=336	RESOLUTE INTEGRITY N=336
TVF [‡]	6.0%	6.9%	7.3%
Cardiac death	1.5%	2.1%	2.1%
TV-MI	2.4%	3.0%	3.3%
TVR	2.4%	2.2%	3.0%
TLF	5.7%	6.6%	5.7%
Major adverse cardiac events	6.8%	8.4%	8.1%
Patient-oriented composite endpoint ^{2§}	10.1%	9.3%	10.5%
Definite or probable ST	0.3%	0.6%	0.6%
Major bleeding	3.0%	3.7%	3.1%



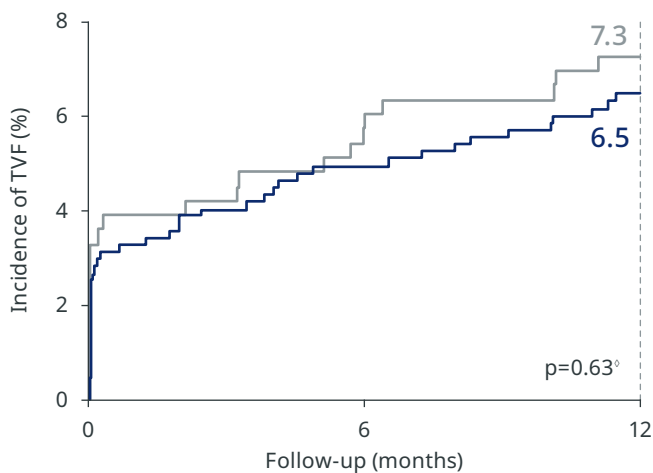
BP-DES showed numerically lower event rates in HBR patients



No significant difference: $p > 0.05$

Orsiro™ demonstrated a numerically lower TVF[†]

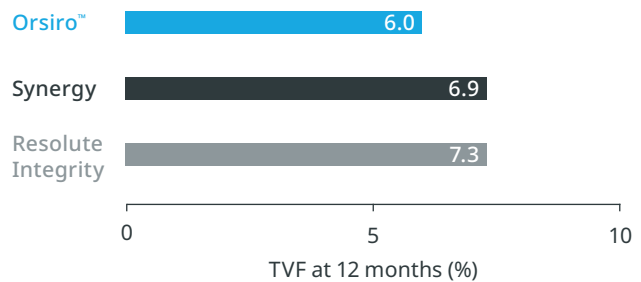
Primary endpoint TVF – at 12 months¹



— BP-DES (Orsiro™ & Synergy)

— DP-DES (Resolute Integrity)

Product level comparison



Differences did not reach statistical significance (Orsiro™ vs. Synergy $p=0.60^{\circ}$, Orsiro™ vs. Resolute Integrity $p=0.49^{\circ}$, Synergy vs. Resolute Integrity $p=0.87^{\circ}$)

Principal investigator: Prof. Clemens von Birgelen, Enschede, the Netherlands

References:

- von Birgelen C et al. High-Bleeding Risk Analysis of the BIO-RESORT Randomized Trial, Comparing 12-Month Clinical Outcome of All comer Patients Treated With Very Thin-Strut Biodegradable Polymer Versus Thin-strut Durable Polymer Drug-Eluting Stents; Presented at: CRT18; March 03, 2018 Washington DC, USA; ClinicalTrials.gov : NCT01674803.
- Zocca P, Kok MM, von Birgelen C, et al. High Bleeding Risk Patients Treated with Very Thin-Strut Biodegradable Polymer or Thin-Strut Durable Polymer Drug-Eluting Stents in the BIO-RESORT Trial. Cardiovascular drugs and therapy. 2018 Aug 24:1-0.

[†]Primary endpoint; Myocardial infarction and stent thrombosis classified according to Academic Research Consortium (ARC) criteria; Major bleeding=BARC 3 or 5 bleeding, or TIMI major bleeding. Values are n (%) [‡]A composite of any death, any MI, or any revascularization. [°]Logrank statistical method

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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BIO-RESORT

5-year outcome of patients with small coronary vessels treated with ultrathin, very thin or thin strut drug-eluting stents in the randomized BIO-RESORT trial¹

Conclusions

- Orsiro™ DES shows a trend towards better efficacy and a similar safety to Synergy and Resolute Integrity in small vessels (<2.5 mm) at 5-year follow-up.
- Orsiro™ DES shows a numerically lower cardiac death event rate in small vessels as well as a numerically lower definite or probable stent thrombosis in small vessels at long term follow-up compared to Resolute Integrity and Synergy.

Study design

Small vessel subgroup (<2,5 mm diameter) of an all-comers, multi-center, assessor and patient-blinded, randomized, non-inferiority trial.

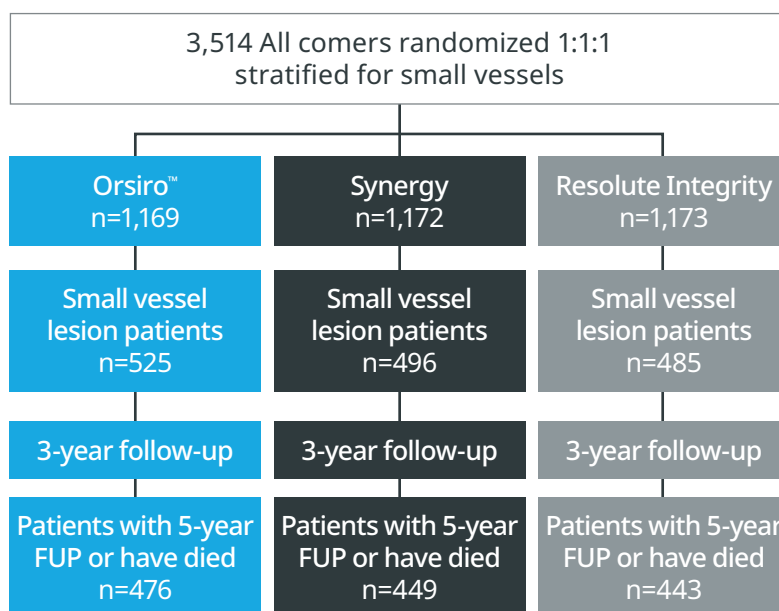
Endpoints

Primary endpoint

- Target Lesion Failure (TLF): composite of cardiac death, target vessel-related myocardial infarction or target lesion revascularisation

Secondary endpoints

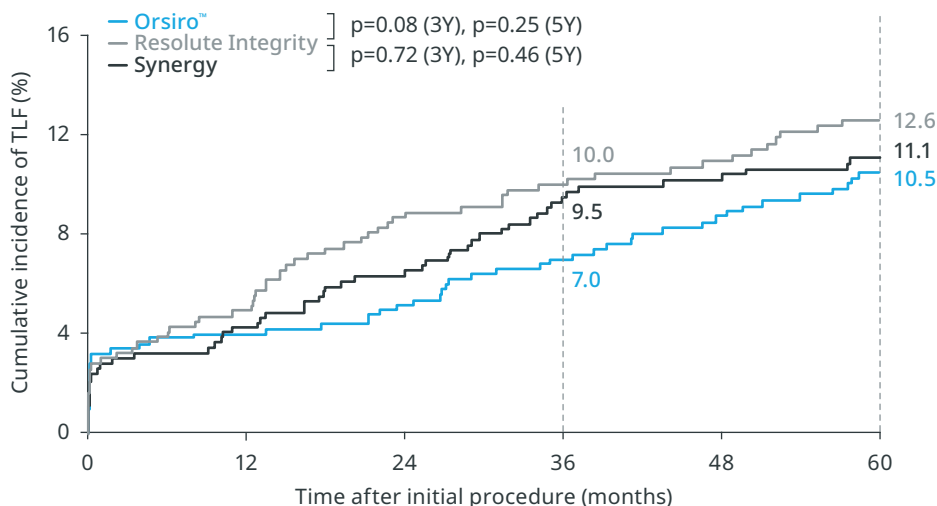
- Cardiac death
- Target Vessel related Myocardial Infarction (TV-MI)
- Target Lesion Revascularisation (TLR)
- Stent Thrombosis (ST)



PATIENT CHARACTERISTICS ¹	ORSIRO N=525		SYNERGY N=496		RESOLUTE INTEGRITY N=485		P-VALUE ORSIRO VS. RESOLUTE INTEGRITY	P-VALUE SYNERGY VS. RESOLUTE INTEGRITY
Age, yrs	64.9±10.2		66.7±9.6		65.5±10.9		0.19	0.91
Female	158	30.1 %	142	28.6 %	149	30.7 %	0.83	0.47
Diabetes mellitus	101	19.2 %	106	21.4 %	102	21.0 %	0.48	0.90
Current smoker	133 ^a	25.9 %	128 ^b	26.8 %	129 ^c	27.2 %	0.63	0.90
Previous myocardial infarction	95	18.1 %	87	17.5 %	109	22.5 %	0.08	0.05
Previous PCI	103	19.6 %	93	18.8 %	86	17.7 %	0.44	0.68
Previous CABG	33	6.3 %	42	8.5 %	35	7.2 %	0.56	0.47
Lesion characteristics (n=1,819)	n=636		n=581		n=602			
Complex lesion (type B2 or C)	452	71.4 %	399	68.7 %	380	63.3 %	0.002	0.053
CTO	24	3.8 %	21	3.6 %	26	4.3 %	0.63	0.54
Severe calcification	113	17.8 %	111	19.1 %	126	20.9 %	0.16	0.43
In-stent restenosis	3	0.5 %	12	2.1 %	13	2.2 %	0.009	0.91

^aOrsiro™ n=514 ^bSynergy n=477 ^cResolute Integrity n=475

Primary Endpoint^{1,2}

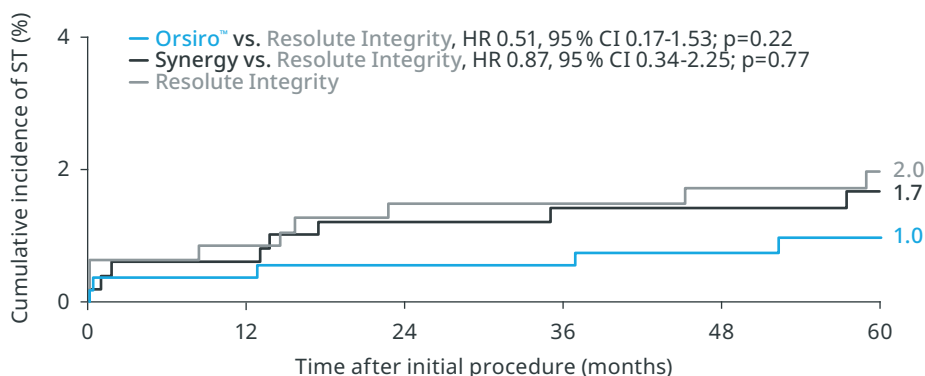


Orsiro™ DES shows a trend towards better efficacy in small vessels (<2.5mm)^{*,2}.

Secondary Endpoints²

TLF COMPONENTS AT 5 YEARS ²	ORSIRO N=525	SYNERGY N=496	RESOLUTE INTEGRITY N=485	P-VALUE ORSIRO VS. RESOLUTE INTEGRITY	P-VALUE SYNERGY VS. RESOLUTE INTEGRITY
TLF	10.5 %	11.1 %	12.6 %	0.25	0.46
TLR	4.4 %	4.7 %	6.8 %	0.08	0.18
Cardiac death	2.8 %	3.4 %	4.2 %	0.27	0.57
TV-MI	4.9 %	4.4 %	4.4 %	0.86	0.94

Definite or probable Stent Thrombosis²



Principal investigator: Eline H. Ploumen MD PhD, Thoraxcentrum Twente, Enschede, the Netherlands

References:

- von Birgelen C. et al. The Lancet. 2016;388(10060): 2607-17.
- Ploumen E. H., Five-year outcome of patients with small coronary vessels treated with ultrathin, very thin or thin strut drug-eluting stents in the randomized BIO-RESORT trial Presented at euroPCR 2022, Paris.

* Based on TLF and TLR rates, compared to Synergy DES and Resolute Integrity DES, at 5 years, BIO-RESORT 5Y small-vessels subgroup, Presented by E.Ploumen at euroPCR 2022.
** Compared to Resolute Integrity and Synergy, based on the 5-year outcomes from the BIO-RESORT small-vessels subgroup.

DES: Drug Eluting Stent RCT: Randomized Controlled Trial TLR: Target Lesion Revascularization TV-MI: Target Vessel Myocardial Infarction MI: Myocardial Infarction ST: Stent Thrombosis.

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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BIO-RESORT

60-month primary endpoint results of an RCT comparing Orsiro™ DES and Synergy vs. Resolute Integrity – Diabetic Subgroup Analysis

Conclusions

- The prespecified sub-group analysis in patients with diabetes revealed no difference in the main clinical endpoint, yet cardiac mortality was found to be lower with Orsiro™ DES vs. Resolute Integrity.
- At 5 years, Orsiro™ DES shows significantly lower cardiac death events in diabetic patients in comparison to Resolute Integrity (p-value=0.03).

Study design

All-comers, multi-center, assessor and patient-blinded, randomized, non-inferiority trial.

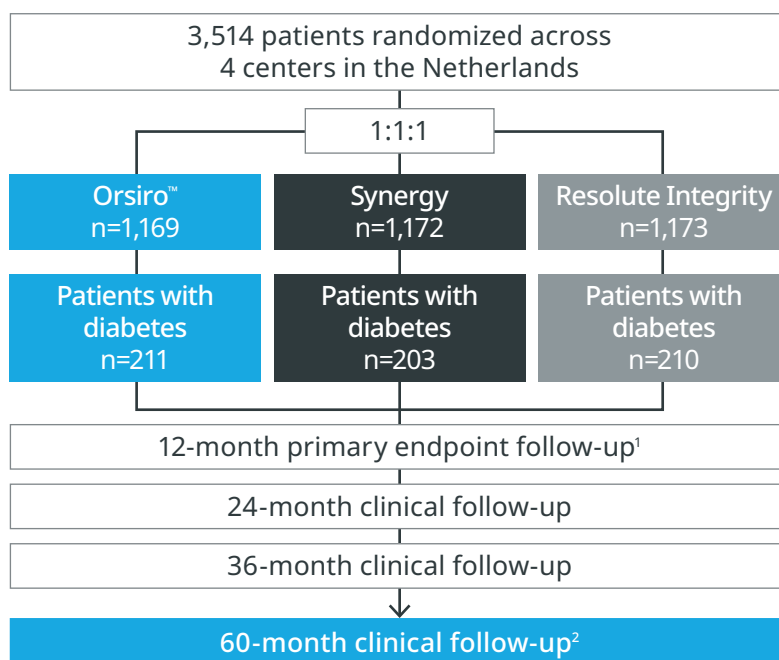
Endpoints

Primary endpoint

- Target Vessel Failure (TVF) at 12 months defined as the composite of:
 - Cardiac Death
 - Target Vessel-Myocardial Infarction (TV-MI)
 - Target Vessel Revascularisation (TVR)

Secondary endpoints

- Death
- Myocardial Infarction (MI)
- Revascularisation rate
- Stent Thrombosis (ST)
- Target Lesion Failure (TLF)
- Major Adverse Cardiac Events (MACE)
- Patient-Oriented Composite Endpoint (POCE)

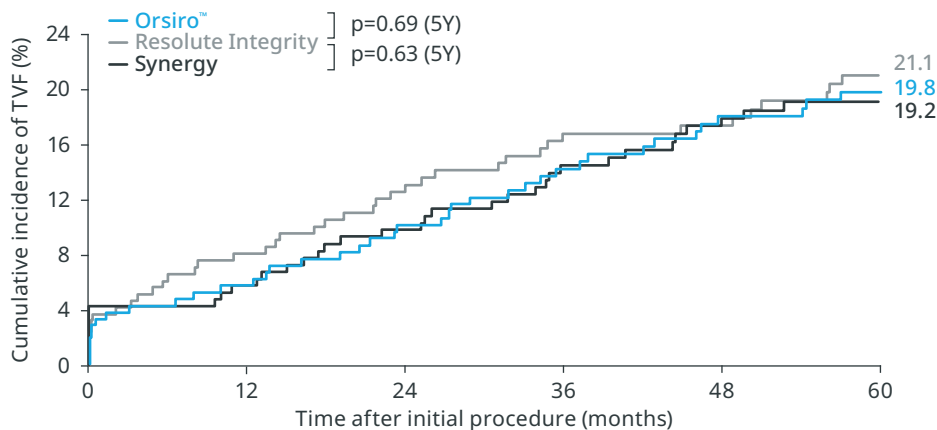


PATIENT CHARACTERISTICS WITH DIABETES	ALL PATIENTS N=624		ORSIRO N=211		SYNERGY N=203		RESOLUTE INTEGRITY N=210		P-VALUE
Age, yrs	66.5±10.1		67.1±9.6		66.7±9.6		65.5±10.9		0.25
Female	200	32.1 %	65	30.8 %	61	30.0 %	74	35.2 %	0.47
Body mass index (kg/m2)	29.3±4.7		29.7±4.4		29.3±4.9		29.1±4.7		0.41

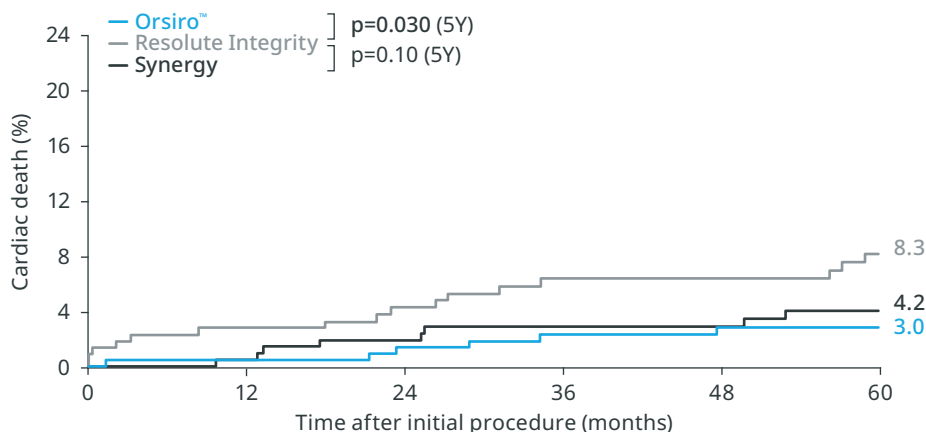
Medical history									
Previous MI	149	23.9 %	54	25.6 %	40	19.7 %	55	26.2 %	0.23
Previous PCI	157	25.2 %	56	26.5 %	57	28.1 %	44	21.0 %	0.21
Previous CABG	81	13.0 %	27	12.8 %	29	14.3 %	25	11.9 %	0.77
Acute coronary syndrome	380	60.9 %	129	61.1 %	127	62.6 %	124	59.0 %	0.76

LESION CHARACTERISTICS WITH DIABETES	ALL PATIENTS N=624		ORSIRO N=211		SYNERGY N=203		RESOLUTE INTEGRITY N=210		P-VALUE
At least 1 complex lesion	493	79.0 %	174	82.5 %	151	74.4 %	168	80.0 %	0.12
At least 1 CTO	33	5.3 %	13	6.2 %	12	5.9 %	8	3.8 %	0.50
At least 1 bypass graft lesion	19	3.0 %	5	2.4 %	5	2.5 %	9	4.3 %	0.44
At least 1 severely calcified lesion	162	26.0 %	54	25.6 %	53	26.1 %	55	26.2 %	0.99

Primary Endpoint - Target Vessel Failure¹

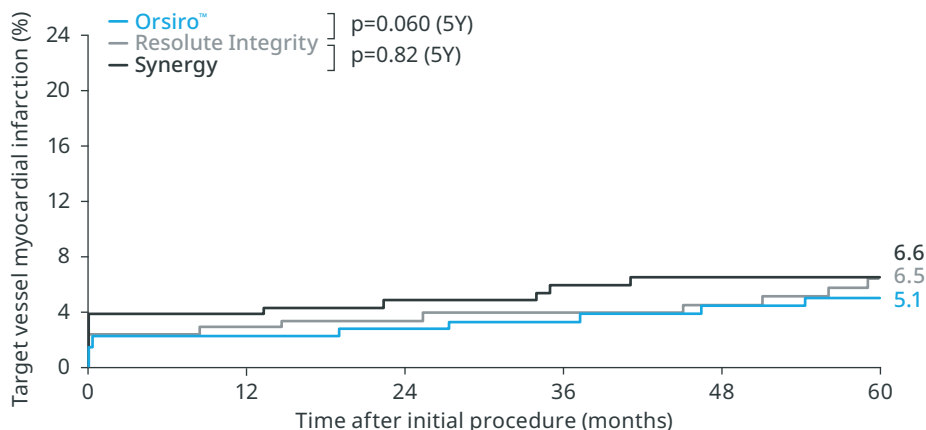


Secondary Endpoint - Cardiac Death¹



64%
 $p=0.03$
 significantly lower
 cardiac death events
 with Orsiro™¹

Secondary Endpoint - Target Vessel Myocardial Infarction¹



Orsiro™ DES shows
 numerically lower
 TV-MI events in
 diabetic patients at
 5 years.¹

Principal investigator: Eline H. Ploumen MD PhD, Thoraxcentrum Twente, Enschede, The Netherlands

¹In comparison to Resolute Integrity in diabetic patients at 5 years, based on the 5-year outcomes of the BIO-RESORT trial.

TVF: Target Vessel Failure TV-MI: Target Vessel-Myocardial Infarction TVR: Target Vessel Revascularisation MI: Myocardial Infarction ST: Stent Thrombosis
 TLF: Target Lesion Failure MACE: Major Adverse Cardiac Events.

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